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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,603	03/08/2007	Rene Djurup	DJURUP2	2533

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EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
08/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,603	DJURUP ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-16,18,19,21,24,26,29,44,48-55 and 58-60* is/are pending in the application.

4a) Of the above claim(s) *8,9,14-16,21,44,48-55 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6, 7, 10-13, 18, 19, 24, 26, 29 and 58-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 05/14/2009, has been entered.

Claims 2-5, 17, 20, 22-23, 25, 27-28, 30-43, 45-47 and 56 have been canceled.

Claims 58-60 have been added.

Claims 1, 6-16, 18-19, 21, 24, 26, 29, 44, 48-55 and 58-60 are pending.

2. This Action will be in response to Applicant's Arguments/Remarks, filed 05/008/2009.

The rejections of record can be found in the previous Office Action, mailed 10/17/2008.

Election/Restrictions

3. Applicant asserts that because claim 1 has been amended to limit the claimed antibody to bind residues 20-44 of SIDI (believe to be a typo for hHBP), the claims now are distinct from Flodgaard, hence the dependent method claims should be rejoined. In response, it is noted that the Restriction Requirement was deemed proper and made final on the claims as they were *originally presented*, filed 03/08/2007, wherein the claims, at the time the Restriction Requirement was made, read on an antibody that was not limited to binding residues 20-44 of hHBP. Therefore, the restriction requirement stands.

With regard to rejoinder, Applicant is directed to the following:

> The examiner has required restriction between product and process claims. **Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.** All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.
>
> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all

> criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 8, 9, 14-16, 21, 44, 48-55 and 57 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention/species, there being no allowable generic or linking claim.

Claims 1, 6, 7, 10-13, 18, 19, 24, 26, 29 and 58-60 are currently under examination as it reads on a pharmaceutical composition comprising a monoclonal anti-hHBP antibody that binds residues 20-44 of hHBP.

4. The previous claim objection has been withdrawn in view of applicant's amendment, filed 05/14/2009.

5. The previous written description and enablement rejections under 35 USC 112, first paragraph, regarding "homologues of hHBP" and the biological deposit for F19A5B4 antibody has been withdrawn in view of Applicant's amendment and assurance, filed 05/14/2009.

6. The previous rejection under 35 U.S.C. 102(b) as being anticipated by Flodgaard et al. (WO 00/66151) has been withdrawn in view of Applicant's amendment and assurance, filed 05/14/2009.

Claim Rejections - 35 USC § 112 second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Newly added claims 59-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The present claims are indefinite in the recitation of "at least about 15%" because the specification does not provide any indication as to what range of specific activity is covered by the term "about". As such, the metes and bounds of the instant claims are ambiguous and ill-defined.

*The **new grounds of** rejection are necessitated by Applicant's amendment.*

Claim Rejections - 35 USC § 112 first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 59-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

*This **New Matter** rejection is necessitated by Applicant's amendment.*

Currently the newly added claims contain new matter in the recitation of "by at least about 15%" in claim 59 and 60.

Applicant's amendment, filed 05/14/2009, contains new matter in the newly added claims. However, the specification as-filed, does not provide sufficient written description for the above-mentioned limitations.

Upon reviewing of the present application as-filed, the written support of the newly added limitation mentioned above is not readily apparent.

It appears Applicant relies upon the data presented in Tables 1 and 2 in the specification for the support for the newly added limitation (see pages 36-37). However the data shown in Tables 1 and 2 does not appear to correlate "at least about 15%" in reduction of IL-6 production by the antibody. Therefore the amended claims are not commensurate in scope with the disclosure as-filed.

The instant claims now recite limitation which was not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitation recited in the present claims, which did not appear in the specification, as-filed, introduce new concept and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, Applicant is invited to provide sufficient written support for the limitations indicated above. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1, 7, 10-13, 18, 19, 26, 29 and 58-60 are rejected under 35 U.S.C. 103(a) as being obvious over Pereira et al. (U.S. Patent 5,458,874, cited on IDS) in view of Flodgaard et al. (WO 00/66151, cited IDS, see entire document).

Applicant's argument has been considered but has not been found convincing for reasons of record and reiterated herein for Applicant's convenience.

Pereira et al. teach an antibody that binds to the epitope within the

sequence consisting of amino acid residues 20-44 of hHBP set forth in SEQ ID NO: 1 (see below sequence alignment). It is noted that hHBP is also known as CAP37 (see page 1, line 31 of the instant specification).

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NQGRHFCGGALIHARFVMTAASCFQ      a.a. 20-44 of SEQ ID NO: 1
||||||||||||||||||||||||||
NQGRHFCGGALIHARFVMTAASCFQ      SEQ ID NO: 8 of Pereira et al.
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Pereira et al. teach a bioactive peptide of hHBP (SEQ ID NO: 8) and polyclonal and monoclonal antibodies that binds the peptide (see column 3, lines 28-33 and column 36, lines 22-67). Furthermore, Pereira et al. teach a hybridoma cell producing the antibody (see column 36, lines 58-62).

Although Pereira et al. do not explicitly teach the characterization of the antibody, i.e., *inhibiting at least one inflammatory response associated with hHBP in the absence or presence of a bacterial product*, given that Pereira taught the same or nearly the same antibody binding to the same epitope, the prior art antibody would necessarily inhibit at least one inflammatory response associated with hHBP in the absence or presence of a bacterial product.

Since the Office does not have a laboratory to test the prior art antibody, it is Applicant's burden to show that the prior art antibody does not inhibit at least one inflammatory response associated with hHBP.

Pereira et al. do not teach a pharmaceutical composition comprising the antibody, *per se*. However, given the explicit teaching of Pereira et al. in that the antibody can be used to screen patients for diagnostic purposes (see column 36, lines 63-68; column 40, lines 56-60), it would have been obvious to one of ordinary skill in the art, at the time of the invention was made, to put the antibody in a pharmaceutical composition, as evidenced by Flodgaard et al. (see page 22, first complete paragraph). In particular, Flodgaard et al. teach a pharmaceutical composition comprising antibodies to hHBP for diagnosing whether a patient produces hHBP (see paragraph bridging pages 22-23).

A person of ordinary skill in the art would have been motivated to include the antibody taught by Pereira et al. in a pharmaceutical composition to be used for screening and diagnostic purposes as taught by both Pereira and Flodgaard.

It is noted that although motivation to combine the prior art teaching (i.e. for diagnostic purposes) is different from the intended use provided by the claims, i.e., "for modulating at least one inflammatory response"; such intended use does not distinguish the composition in the art. See e.g. MPEP § 2114.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In response to Applicant's argument that Pereira's antibody was taught in present tense thus it is unclear whether they were actually practiced, it is noted that given the clear teaching by Pereira regarding the antibody that binds residues 20-44 of hHBP, it

would be well within the technical grasp of one of ordinary skill in the art to make such antibody.

Furthermore, Applicant argues that there is no recognition that the antibody to hHBP (20-44) inhibits IL-6 production thus there was no motivation to find an anti-hHBP20-44 antibody with the recited characteristics (i.e., reducing IL-6 levels in whole blood). In response, it is noted that Pereira taught the same or nearly the same antibody binding to the same epitope, therefore, the prior art antibody would necessarily have those characteristics.

Applicant's argument has not been found convincing. Therefore, this rejection is hereby maintained for reasons of record as it applies to amended and newly added claims.

Allowable Subject Matter

13. Cell clone F19A5B4 appears to be free of prior art. Applicant's willingness to limit the independent claim to F19A5B4 has been acknowledged.

Conclusion

14. No claim is allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Examiner, Art Unit 1644
July 27, 2009

/Phillip Gambel/
Primary Examiner
Technology Center 1600
Art Unit 1644
August 2, 2009